EXHIBIT 12

GAO

United States General Accounting Office

Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

January 1994

PRESCRIPTION DRUGS

Companies Typically Charge More in the United States Than in the United Kingdom





United States General Accounting Office Washington, D.C. 20548

Health, Education, and Human Services Division

B-251664

January 12, 1994

The Honorable Henry A. Waxman Chairman, Subcommittee on Health and the Environment Committee on Energy and Commerce House of Representatives

Dear Mr. Chairman:

As the U.S. debate over health care reform unfolds, a major controversy concerns the appropriate level of prescription drug prices. Although outpatient prescription drugs represented only about 5 percent of total 1991 U.S. health care expenditures, the recent pace of drug price increases has heightened the visibility of prescription drug costs. During the 1980s, prescription drug prices increased at rates higher than the average rate of inflation in the overall economy. While the rate of prescription drug price increases (as measured by the consumer price index for prescription drugs) has slowed since 1990, public discontent over the high cost of drugs in the United States persists as consumers and policymakers look to other countries where a perception exists that drugs are sold more cheaply.

In light of public and congressional interest in prescription drug pricing, you asked that we examine the extent to which drug manufacturers charge more for the same products in the United States than abroad. In addition, you asked that, in studying manufacturers' "factory prices," we identify, to the extent possible, the causes of any documented price differentials. In a previous report, we compared factory prices for frequently dispensed prescription drugs in the United States with the prices of the identical drugs sold in Canada. In this report, we present the results of our comparison of factory prices for frequently dispensed prescription drugs sold in both the United States and the United Kingdom (U.K.).

Our study focuses on factory prices, brand-name drugs, and the market segment in which retail pharmacies generally do not receive manufacturers' discounts. Given this focus, we examined the top 200 prescription drug products most frequently dispensed in 1991 in the United States. These 200 drugs accounted for the majority (54.9 percent)

¹Pharmaceutical prices can be measured at different points in the distribution chain. Retail prices are paid by consumers to pharmacists. Wholesale prices are paid by pharmacists to wholesalers. Factory prices—which our study focuses on—are paid by wholesalers to manufacturers.

²See Prescription Drugs: Companies Typically Charge More in the United States Than in Canada (GAO/HRD-92-110, Sept. 30, 1992).

of all prescriptions dispensed in the United States. We succeeded in matching 77 of these popular products with the identical drugs sold in the United Kingdom.³ Our study included only products for which the same manufacturer sold or licensed the identical product in both countries in the same form and dosage strength.

Background

Both the differences and the similarities between the United States and the United Kingdom make a comparison between the two countries' pharmaceutical sectors illuminating. While pharmaceutical companies in the two countries are similar in several respects, U.S. and U.K. firms face very different market conditions.

The United Kingdom, like the United States but unlike Canada, is home to a strong, research-oriented pharmaceutical industry. The U.K. pharmaceutical industry, which consists of privately owned and operated companies, remains with the United States as one of the world's leaders in pharmaceutical research and development. The United Kingdom ranks third in the world—behind only the United States and Japan—in the number of major global drugs introduced between January 1970 and May 1992. As of 1991, three of the world's 20 top-selling pharmaceutical firms were based in the United Kingdom, including the world leader, Glaxo.

Despite the similarity between the two industries, firms in the United Kingdom operate in a very different market environment compared with companies in the United States. The United Kingdom has a much smaller market, with a population about one-fifth the size of the United States. Furthermore, in the United Kingdom, the prescription drug market is dominated by the government, which reimburses nearly all prescription drug purchases and regulates drug company profits. By contrast, the U.S. market is dominated by private payers, including many consumers who lack insurance coverage to pay for prescription drugs and who pay prices for pharmaceuticals that are not subject to regulation. While the U.K. government is tantamount to the single purchaser of prescription drugs in

³We lack data for estimating the share of the market represented by these 77 drugs.

⁴Heinz Redwood, "New Drugs in the World Market: Incentives and Impediments to Innovation," <u>The</u> American Enterprise, Vol. 4, No. 4 (1993), p. 77.

⁶Although many U.S. citizens enjoy prescription drug coverage through private insurance or Medicaid, many others—especially those with modest incomes—do not. In the most recent estimate that we identified, the U.S. Office of Technology Assessment estimated that in 1987, 73 to 77 percent of noninstitutionalized U.S. citizens under age 65 had some outpatient prescription drug coverage, but only 43 to 46 percent of U.S. citizens over age 65 had outpatient prescription drug insurance. See Pharmaceutical R&D: Costs, Risks and Rewards, U.S. Congress, Office of Technology Assessment, Pub. No. OTA H-522 (Washington, D.C.: Feb. 1993), p. 241.

that country, the U.S. pharmaceutical market is characterized by many buyers. As a result, U.S. drug manufacturers can offer lower prices to certain buyers, like mail order pharmacies and some managed care organizations, while charging relatively higher prices to other buyers, such as wholesalers who serve typical retail pharmacies.

Since 1980, the United States has experienced greater drug price increases than has the United Kingdom. Between 1980 and 1991, U.K. pharmaceutical prices declined an average of 1.3 percent per year, after adjusting for overall inflation.⁶ By contrast, U.S. pharmaceutical prices increased by an average of 3.4 percent per year, after adjusting for overall inflation.⁷ (However, since 1990, consistent with drug manufacturers' public pledges of self-restraint in pricing, the growth in U.S. drug prices has declined.)

Scope and Methodology

The results of our analysis are restricted to the May 1, 1992, prices of the drugs that we analyzed and cannot be projected beyond the scope of our study. In addition, our study is based on the prices for which drug manufacturers sell their products to wholesalers; it does not measure retail prices paid by consumers for drugs at pharmacies in the United States or the United Kingdom.⁸ As agreed with your office, we defined the scope of our study as follows.

First, for the identical drugs sold in the United States and the United Kingdom, we compared manufacturers' factory prices. We focused on these prices because—unlike wholesale or retail prices—factory prices allow us to determine whether drug manufacturers are charging higher prices in the United States for drugs sold in both countries. Further, manufacturers' charges are a significant component of final consumer costs as they account for roughly two-thirds of the final or retail average prescription charge in the United States.

Second, we studied the prices of brand-name drugs. In focusing on the manufacturer's role in pricing, we compared the factory prices of the identical drugs sold in the United States and the United Kingdom by the

 $^{^6}$ In addition, in recent negotiations, drug manufacturers and the U.K. government agreed to a one-time prescription drug price cut of 2.5 percent to remain in effect for 3 years beginning October 1, 1993.

²These figures are based on pharmaceutical prices, which include both prescription and over-the-counter products. Data were not available to calculate a comparable price index for prescription drugs alone.

⁸Both wholesale and retail margins for pharmaceuticals are also regulated in the United Kingdom.

same manufacturers (or their foreign affiliates). This same manufacturer criterion led us to exclude generic drugs from our sample because generic drugs are usually manufactured and sold in the United States and other countries by different, unaffiliated companies.⁹

Third, we concentrated our analysis on that segment of the drug market populated by the typical consumer who, in both the United States and the United Kingdom, buys prescription drugs at retail pharmacies. We focused our study on this market segment because in the United States these consumers are relatively vulnerable to high drug prices. Although these consumers account for at least 55 percent of all outpatient prescriptions in 1992, they generally do not benefit from discounts that certain purchasers, such as hospitals, mail order pharmacies, and certain health maintenance organizations (HMOS), may obtain from manufacturers.

We summarized the spectrum of differences in drug prices between the United States and the United Kingdom by constructing a price index that accounts for differences in the quantities of each drug sold in the United States. To identify the likely causes of drug price differences across countries, we interviewed U.K. government officials, as well as industry representatives and academic experts in both countries.

To provide perspective on our central findings, we conducted additional price comparisons. First, to permit us to contrast the typical consumer's perspective on factory prices of drugs with the manufacturer's perspective, we also estimated U.S.-U.K. price differentials using an average U.S. price measure that includes discounts and rebates provided to certain nonfederal institutional buyers. 10 The average U.S. price does not address our central question—how factory prices differ between the market segments frequented by typical consumers in the United States and the United Kingdom. Nonetheless, the average U.S. price does help shed light on a related question that is vital to manufacturers—how the amount of revenue per package received by the manufacturers differs between the United States and the United Kingdom. Second, because lower priced generic drugs are available as alternatives to some higher priced brand-name drugs, we also estimated the price differential that would occur if American consumers always substituted generic drugs, if available, for the brand-name drugs in our sample.

 $^{^9\}mathrm{As}$ of 1993, generic drug products comprised an estimated 30 percent of prescriptions filled in the United States.

¹⁰We compared this alternative measure of U.S. prices (for the same market basket of frequently dispensed drugs in the United States) to the factory prices charged for the same drugs in the United Kingdom.

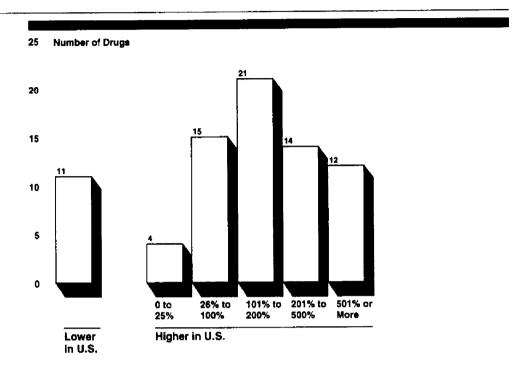
We conducted our review from April 1992 through July 1993 in accordance with generally accepted government auditing standards. Details of our scope, methodology, and analysis are described in appendix I. The individual drug price differentials appear in appendix II. Methodological issues for international drug price comparisons are discussed in appendix III.

Principal Findings

Manufacturers Typically Charge More for Prescription Drugs in the United States Than in the United Kingdom We found significant differences in the prices that manufacturers charge wholesalers for identical, frequently dispensed prescription drugs sold in retail pharmacies in the United States and the United Kingdom. A market basket of 77 frequently dispensed drugs that we analyzed would cost wholesalers 60 percent more in the United States than in the United Kingdom. A total of 66 drugs (86 percent) were priced higher in the United States than in the United Kingdom, and 47 (61 percent) were priced more than twice as high in the United States as in the United Kingdom. U.S.-U.K. drug price differentials varied substantially among individual products. U.S. prices ranged from 62 percent lower to 1,712 percent higher than the U.K. prices, as figure 1 shows.

¹¹This market basket is, in effect, an index that weights each individual drug price by the quantity of the product sold in the United States in 1992. The overall price differential was calculated by converting U.K. prices to U.S. dollars using the May 1, 1992, exchange rate. We also calculated the differential using an alternative conversion method, the 1992 purchasing power parity. Using this method, the U.S.-U.K. price differential was 86 percent.

Figure 1: Range of U.S.-U.K. Drug Price Differentials



Price Differentials Smaller for Newer Medicines and Single-Source Drugs Price differentials tended to be dramatically smaller for more recently introduced drugs in our sample than for older products. In our sample, the market basket of drugs introduced before 1980 cost 120 percent more in the United States than in the United Kingdom, while the market basket of drugs first introduced between 1980 and 1985 cost 60 percent more in the United States, and the market basket of drugs introduced between 1986 and 1992 cost 17 percent more in the United States. This pattern is consistent with both the effect of U.K. restrictions on price increases and with reports that manufacturers have narrowed country-by-country differences in the introductory prices of new drugs in recent years.

In addition, price differentials tended to be smaller for single-source brand-name drugs in our sample than for brand-name drugs that have generic substitutes. For example, the market basket of drugs that were multiple source in both countries cost 125 percent more in the United States than in the United Kingdom, while for single-source drugs the corresponding difference was 45 percent. Because drugs with generic substitutes have usually been on the market longer, this finding is consistent with our result that older drugs have wider price differentials. In addition, this result is consistent with findings from other studies that suggest that, in the U.S. market, manufacturers respond to competition

from lower priced generic drugs by increasing—rather than decreasing—the prices of brand-name products.

Methodological Choices Do Not Significantly Alter Qualitative Results

In conducting international comparisons of drug prices, the precise size of drug price differentials depends on the methodological choices made. Other researchers might make different decisions than we did and, consequently, report price differentials that are smaller or larger than what we found. Nonetheless, our qualitative result—that prescription drug prices are significantly higher in the United States than in the United Kingdom—is largely unaffected by the methodological decisions we made.

Some of these methodological choices depend on the particular question being asked. Consider the following examples:

- Other researchers might be concerned with how manufacturers' factory
 prices charged in the United Kingdom compare to the average factory
 prices paid by all market segments in the United States (including those
 who have access to manufacturers' discounts), rather than to the segment
 consisting of the typical U.S. consumer. We found, however, that whether
 one looks at the typical consumer market segment or the entire market
 had a modest impact on the overall price differential.
- Others may also want to calculate how price differentials vary when accounting for the possibility that consumers can sometimes buy less expensive generic substitutes. We found that, for the brand-name drugs in our sample, if U.S. consumers purchased lower priced generic substitutes when available, and U.K. consumers did not, U.S. consumers would still pay substantially more for our market basket of drugs.¹²

Other choices relate to the more technical issues of performing an international drug price comparison, such as how to convert U.K. prices into U.S. dollars. For example, we still found substantial drug price differentials by using the 1992 purchasing power parity (rather than the May 1, 1992, exchange rate) to express U.K. drug prices in U.S. dollars. There was also little change in the results when we used either the second quarter 1992 exchange rate or the 1992 average exchange rate to convert pounds sterling to dollars. These rates were similar to the May 1, 1992, exchange rates.

¹²Generic substitutes were available for 21 of the 77 brand-name drugs in our sample.

Primary Factors Contributing to U.S.-U.K. Price Differentials

Most of the differences in prescription drug prices between countries cannot be attributed to differences in manufacturers' costs. This conclusion holds for differences in costs whether they are associated with research and development, marketing, production, or distribution. Pharmaceutical manufacturers' officials and industry experts agree that cost differences are not a major factor in determining prices for individual drug products.

Instead, we found that U.S.-U.K. drug price differences are primarily due to the regulatory constraints that manufacturers face in pricing their drugs on the U.K. market and to the lack of similar constraints in the United States. In the United Kingdom, the government, operating within a health system that is publicly financed and run, is tantamount to the sole payer for prescription drugs. The U.K. government exercises its concentrated buying power through an agreement with drug manufacturers; this agreement limits the profits that drug manufacturers earn on sales in the United Kingdom. Although manufacturers are generally free to set the introductory prices of newly released drugs in the United Kingdom, each manufacturer's profits must not exceed the maximum level established by the government. Furthermore, once introductory prices are set, the government restricts manufacturers from increasing prices on existing products. In the Institute of the price of the pric

Qualitative evidence suggests that other competitive factors in the U.K. market may work together to lower average brand-name drug prices:

 Pharmaceutical information is more widely available in the United Kingdom than in the United States, perhaps enhancing price competition among drug manufacturers in the United Kingdom. U.K. physicians receive information on their own prescribing patterns and on the comparative prices and efficacy of drugs. In addition, physicians in the United Kingdom are given prescribing benchmarks, referred to as indicative amounts, that

¹³In our previous international comparison of drug prices, we reached similar conclusions: a major source of U.S.-Canadian drug price differentials was the combined actions in the drug marketplace of Canadian federal and provincial governments to restrain prescription drug prices. See <u>Prescription Drugs</u>: Companies Typically Charge More in the United States Than in Canada, pp. 2-3.

¹⁴The agreement between drug manufacturers and the U.K. government was recently renegotiated. Under the new agreement, prescription drug prices in the United Kingdom were cut by 2.5 percent for 3 years, effective October 1, 1993.

- encourage them to be aware of the prices of the drugs they prescribe and how their prescribing patterns compare to national averages.¹⁵
- The government can remove drugs in certain therapeutic categories from its list of reimbursable products if the manufacturers' prices for those drugs are considered excessive.
- Wholesalers and retailers can import brand-name drug products into the
 United Kingdom from other European countries where drugs are available
 at lower prices (known as parallel importing). Parallel importing may
 exert downward pressure on prices of some brand-name drugs, thereby
 contributing to lower average U.K. drug prices.

Implications of U.K.-Style Government Intervention in the U.S. Market Remain Unclear

Although government regulation has restrained drug prices in the United Kingdom, the implications of similar intervention in the U.S. pharmaceutical market are unclear. Little agreement exists on the appropriate level of U.S. drug prices, and no consensus has emerged on what, if any, mechanism should be used to achieve this price level. Regulatory approaches used in the United Kingdom, while apparently effective at restraining drug prices in that country, may not be easily transferrable to the United States because of the many institutional differences between the two countries. In addition, the debate over the potential effects of drug price regulation—particularly the contention that higher drug prices encourage pharmaceutical research and development—cannot be resolved solely by referring to U.K. drug prices. This larger issue is beyond the scope of our study.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to interested congressional

¹⁶U.K. physicians' indicative amounts are based on such factors as historic expenditures, the comparable average cost for the region, demographics, and inflation. These indicative amounts are not cash limits, but rather a benchmark target for physicians.

committees and make copies available to others upon request. If you or your staff have any questions about this report, please contact me at (202) 512-7119. Major contributors to this report are listed in appendix IV.

Sincerely yours,

Sarah F. Jaggar

Director, Health Financing

and Policy Issues

Case 1:01-cv-12257-PBS	Document 6208-13	Filed 06/29/09	Page 14 of 24

Contents

Letter		1
Appendix I Prices for Many Top-Selling Prescription Drugs Are Higher in the United States Than in the United Kingdom	U.S. Pharmaceutical Market Under Increased Scrutiny U.K. Pharmaceutical Sector Characterized by Slow Price Growth, Universal Insurance, and Strong Research and Development Scope Approach Manufacturers' Prices for Top-Selling Drugs Typically Higher in the United States Than in the United Kingdom	14 14 15 16 18 21
Appendix II Differences in Manufacturers' U.S. and U.K. Prescription Drug Prices (May 1, 1992)		36
Appendix III Methodological Issues for International Prescription Drug Price Comparisons	Purpose of the Study Affects Price Concept Measured Purpose of Study Suggests Criteria for Sampling Decisions Choice of Population and Sample of Drugs Study Focus Influenced Presentation of Results Conclusion	42 42 43 44 48 50
Appendix IV Major Contributors to This Report		52
Table	Table I.1: The Five Most Commonly Dispensed Drugs Illustrate Range of U.SU.K. Price Differentials	24
Figures	Figure 1: Range of U.SU.K. Drug Price Differentials Figure I.1: Range of U.SU.K. Drug Price Differentials	6 22

Contents

Figure I.2: Many Drugs Have Factory Prices Over Twice as High	23
in the United States as in the United Kingdom	
Figure I.3: Large U.SU.K. Price Differentials Persist After	25
Accounting for Discounts in Other U.S. Market Segments	
Figure I.4: More Recently Introduced Drugs Have Smaller	27
U.SU.K. Price Differentials	
Figure I.5: Drugs With Multiple Sources in the United States and	29
the United Kingdom Have Larger U.SU.K. Price Differentials	

Abbreviations

CPI	consumer price index
НМО	health maintenance organization
IPS	Indicative Prescribing Scheme
NHS	National Health Service
non-FAMP	nonfederal average manufacturer price
PPP	purchasing power parity
PPRS	Pharmaceutical Price Regulation Scheme
VA	Department of Veterans Affairs
WAC	wholesale acquisition cost

We compared the factory prices of identical prescription drugs sold by the same manufacturer in the United States and the United Kingdom. We found that (1) large price differentials existed for top-selling brand-name drugs sold in both countries and (2) these large differences persisted even after accounting for generic drugs and manufacturers' discounts that are provided to some U.S. market segments. Price differentials were smaller for newer medicines and for drugs without generic substitutes.

The drug price differentials we found are primarily due to government intervention in the U.K. pharmaceutical market; the U.K. government regulates drug company profits and restricts firms from increasing prices on existing products. However, because of the many institutional and market differences between the two countries, the implications—and the desirability—of U.K.-style regulations for the United States are unclear.

U.S. Pharmaceutical Market Under Increased Scrutiny

Sharp increases in prescription drug prices during the 1980s heightened congressional interest in the pricing practices of drug manufacturers.² Between 1980 and 1991, the prescription drug component of the U.S. consumer price index (CPI) rose much faster than the economywide CPI.³ However, in the past few years, with calls for government regulation increasing, drug manufacturers made public commitments to self-restraint in drug pricing. Consistent with this new industry stance, since 1990 the rate of prescription drug price increases has slowed.

Policymakers' concerns over U.S. prescription drug prices stem in part from the fact that many Americans, because they lack insurance coverage for prescription drugs, are vulnerable to high drug prices. Although many U.S. citizens obtain prescription drug coverage through employer-sponsored health insurance plans or other third-party payers (including Medicaid), other U.S. consumers can get prescription drugs only by paying

¹An earlier GAO report describes such a price comparison between the United States and Canada. See Prescription Drugs: Companies Typically Charge More in the United States Than in Canada.

 $^{^2}$ In sharp contrast to drug prices in the 1980s, drug prices in the 1970s increased more slowly than overall prices.

³Price indexes provide some indication of the rate of prescription drug price increases as compared with price inflation in the general economy. But some research indicates that prescription drug indexes may over-sample medium-aged drugs that undergo above-average price increases, and under-sample younger products that experience less-than-average price increases, thereby overstating annual average drug price inflation. (See Ernst R. Berndt and others, "Auditing the Producer Price Index: Micro Evidence From Prescription Pharmaceutical Preparations," Working Paper No. 4009, National Bureau of Economic Research (Washington, D.C.: Mar. 1992). Alternatively, indexes may understate annual changes in average drug prices because they generally do not measure the impact of new drugs, many of which enter the market at relatively high prices.

out of pocket. Many of these individuals have little financial cushion available when faced with substantial drug expenses. Furthermore, critics contend that such consumers are often doubly vulnerable—not only do they lack insurance, but they are in a market segment in which drug companies charge higher prices. That is, a manufacturer offers discounts to certain buyers (like mail order pharmacies and some managed care organizations) while charging higher prices to other buyers, such as the wholesalers and retail pharmacies that serve the typical consumer.

Unlike the pharmaceutical markets of other large, industrialized countries, the U.S. market is generally free of government regulations that limit drug manufacturers' prices or profits. Consequently, pharmaceutical manufacturers have set different prices in various U.S. market segments. For example, mail order pharmacies and some health maintenance organizations negotiate directly with the drug manufacturers and may obtain discounts. By contrast, retail pharmacies, which collectively make up at least 55 percent of the prescription drug outpatient market, have been unable to obtain lower drug prices.

U.K. Pharmaceutical Sector Characterized by Slow Price Growth, Universal Insurance, and Strong Research and Development Compared to the United States, prescription drug prices in the United Kingdom have been rising relatively slowly. Between 1980 and 1989, U.K. pharmaceutical prices grew at a rate slightly less than overall inflation. By contrast, U.S. pharmaceutical prices rose, on average, by 3.15 percent per year above the overall inflation rate. Despite the United Kingdom's decline in inflation-adjusted pharmaceutical prices, however, the U.K. government still faced continued growth in pharmaceutical spending. From 1980 to 1989, inflation-adjusted drug spending in the United Kingdom grew each year an average of 2.8 percent. (By comparison, the comparable growth rate for U.S. drug spending was almost 5 percent per year.) As a result, by

⁴As part of efforts to shape a health care reform plan, the Congress and the executive branch are currently considering several methods for restraining prescription drug prices. In addition, some pharmaceutical companies have proposed voluntary price restraint agreements. To date, no federal controls affecting drug prices comprehensively have been enacted. However, in 1990, as part of the Omnibus Budget Reconciliation Act, the Congress required pharmaceutical companies to provide price discounts to state Medicaid programs.

⁵Strictly speaking, only a small fraction of drug manufacturers' sales are to retail pharmacies directly; the bulk of such sales are to wholesalers and to large institutional buyers such as HMOs. Nonetheless, most retail pharmacies are not in a position to benefit from discounts because their wholesalers are not able to negotiate discounts from manufacturers.

⁶These figures are based on pharmaceutical prices, which include both prescription and over the counter products. Data were not available to calculate a comparable index for prescription drugs alone.

1992, the U.K. government spent 10 percent of total health care expenditures on prescription drugs.

In the United Kingdom, the national government significantly affects the business environment for drug manufacturers because it plays a predominant role in the delivery and financing of health care. The National Health Service (NHS), through its regional and district health authorities, offers all citizens a comprehensive package of primary, hospital, and community care services at little or no out-of-pocket charge to the patient. As part of this comprehensive package, the NHS covers the cost of most prescribed drugs. In its role as virtually the sole payer for prescription drugs, the NHS accounts for about 97 percent of all prescription drug expenditures in the United Kingdom. Although U.K. health care is largely financed from general tax revenues, other financing sources include payroll and local taxes, consumer copayments for some prescriptions, and payments by private patients in public hospitals.

While the financing and operation of the U.K. health care system is primarily in government hands, the ownership and operation of the U.K. pharmaceutical industry remains private. In addition, the U.K. pharmaceutical industry is one of the world's leaders in pharmaceutical research and development. The United Kingdom ranked third in the world—behind only the United States and Japan—in the number of major global drugs introduced between January 1970 and May 1992. As of 1991, three of the world's 20 top-selling pharmaceutical firms were based in the United Kingdom, including the world leader, Glaxo.

Scope

In response to the questions posed to us by the Chairman of the Subcommittee on Health and the Environment, we defined the scope of our study in terms of (1) the measure of prices that we analyzed, (2) the segment of the drug market that we examined, and (3) the criteria used to select drugs to study. These are further explained below.

Price Measure

For frequently dispensed drugs in the United States, we compared manufacturers' factory prices to the factory prices charged by the same manufacturers of the identical drugs in the United Kingdom.⁸ Manufacturers' factory prices are a major component of retail drug prices—the factory price accounts for about two-thirds of the average U.S.

⁷Redwood, p. 77.

⁸The factory price is typically paid by wholesalers to manufacturers.

retail price of prescription drugs. The decisive reason for studying factory prices, however, is that these prices are the only measure of price that would allow us to determine whether drug manufacturers sell identical products at different prices here and in other countries.

Segment of Market

We focused on the segment of the retail market that accounts for the majority of prescriptions dispensed in the United States. This segment, which we refer to as the undiscounted market segment, involves retail outlets—both traditional retail pharmacies and managed care organizations—that do not negotiate substantial discounts from drug companies. The undiscounted segment in the United States is populated by the typical consumer who, in the United States as well as in the United Kingdom, generally buys prescription drugs at retail pharmacies. In the United States, these consumers are relatively vulnerable to high drug prices. Although these typical consumers accounted for at least 55 percent of all outpatient prescriptions dispensed in 1992, they usually do not benefit from discounts, such as those negotiated by hospitals, mail order pharmacies, and some HMOS.

Selection Criteria

We selected the drugs for our study from the 200 drugs most frequently dispensed by U.S. drugstores. ¹⁰ These 200 drugs represented 54.9 percent of all prescriptions dispensed in U.S. drugstores during 1991. Drugs often come in multiple dosage forms (tablets and capsules), dosage strengths (100 milligrams), and package sizes (30 and 100 tablets)—each combination (form/strength/package size) with its own price. To simplify our analysis, we selected a single, commonly used U.S. dosage form, dosage strength, and package size for each specific drug product. (When the U.S. package size was not available in the United Kingdom, we followed a methodology detailed in app. III.) We then obtained U.S. and U.K. prices per package for each individual drug product. Finally, we compared unit prices in the United States and the United Kingdom; use of unit prices permits a comparison of otherwise identical products that differ in package size.

⁹Also included in this market segment is a substantial fraction of consumers who belong to HMOs and other managed care organizations. Although some HMOs, especially those that operate in-house pharmacies, negotiate discounts from drug manufacturers, other HMOs do not receive such discounts.

¹⁰A ranking of the 200 drug products most frequently dispensed in the United States is published annually in <u>American Druggist</u>.

Approach

Of the 200 most frequently dispensed drugs, we were able to match 77 drugs by brand name, manufacturer, dosage strength, and dosage form in both the United States and the United Kingdom. (See app. II.) The 77 matched drugs included 27 of the 50 most commonly prescribed drugs. We excluded 123 of the 200 drugs in our sample for one or more of the following reasons:

- The manufacturer did not sell the drug in the United Kingdom in the same dosage strength or dosage form as in the United States (9 drugs).
- The manufacturer discontinued selling the product in the United States before May 1, 1992 (1 drug).
- The drug was sold by prescription in one country but was sold over the counter in the other country (9 drugs).
- The manufacturer selling the drug in the United States did not sell the identical product in the United Kingdom (104 drugs).¹²

This last reason effectively resulted in our studying the prices of brand-name drugs.¹³ The rationale for focusing on brand-name drugs is our interest in the manufacturers' role in pricing, which in turn required us to compare the factory prices of the identical drugs sold in the United States and the United Kingdom by the same manufacturers (or their foreign affiliates).

Given the scope of the study detailed above, we obtained a measure of U.S. factory prices that pertains to the undiscounted market segment—the wholesale acquisition cost (WAC)—from the 1992 Medi-Span Master Drug Data Base-Select. The price data are for May 1, 1992. The WAC represents the factory price for most of the outpatient prescription drug market: the 55 percent of that market served by wholesalers who do not receive

¹¹We lack data for estimating the share of the market represented by these 77 drugs.

¹²This category of excluded drugs includes generic products sold in the United States that were manufactured by a company that had no affiliated company marketing the identical product in the United Kingdom.

¹³We use the term brand-name drugs in this context to mean originator drugs—that is, those pharmaceutical products that introduce a new chemical entity. While some manufacturers of generic drugs may use brand names, these products are not originator brand-name drugs.

¹⁴Medi-Span is a private firm that gathers pharmaceutical information.

discounts from manufacturers and the substantial share of the managed care market segment that also does not receive such discounts. 15,16

To contrast the typical consumer's perspective on factory prices of drugs with the manufacturers' perspective, we also estimated U.S.-U.K. differentials using an average U.S. price that encompasses manufacturers' prices in both discounted and undiscounted market segments. The average U.S. price does not address our central question—how factory prices differ between the market segments frequented by typical consumers in the United States and the United Kingdom. But the average U.S. price does help shed light on a related question that is vital to manufacturers—how the amount of revenue per package received by the manufacturer differs between the United States and the United Kingdom.

To estimate the average manufacturer's price, which summarizes manufacturers' prices in all market segments for prescription drugs in the United States, we obtained the nonfederal average manufacturer price (non-FAMP) from the U.S. Department of Veterans Affairs (VA). The non-FAMP price measure is calculated for a single form, strength, and package size of a specific drug product (for example, Amoxil 250 mg tablet, package of 500). The non-FAMP is a weighted average of the WAC (the factory prices charged to wholesalers in the United States) and the lower prices charged by manufacturers to buyers with market power, like some HMOS. These lower prices reflect manufacturers' discounts and rebates. These lower prices for the period of October 1, 1991, through September 30, 1992, to conform to the period for which we have WAC price data.

Although a comprehensive analysis of U.S.-U.K. price differentials for the broad array of generic drugs sold in the United States lies beyond the

¹⁵HMOs constitute roughly 32 percent of the outpatient prescription drug market; however, many HMOs (especially those that do not operate their own pharmacies) do not receive price discounts from drug manufacturers.

¹⁶Some observers have criticized the use of the WAC as a measure of manufacturers' prices because it does not capture manufacturers' discounts and price reductions provided to certain buyers. However, the WAC is the correct price measure for an analysis of the <u>undiscounted</u> segment of the U.S. pharmaceutical market. Use of a price measure that includes manufacturers' discounts would understate the manufacturer's component of the price paid by the typical U.S. consumer. Consequently, the true differential in manufacturers' prices for this market segment would be underestimated.

¹⁷The non-FAMP price measure excludes prices paid by the VA, the U.S. Public Health Service, other federal buyers, and rebates paid by state Medicaid programs. These buyers may receive discounts or rebates from drug manufacturers.

¹⁸The Secretary of the Department of Veterans Affairs defines the period of time for which manufacturers calculate the non-FAMP. The non-FAMP period that covers May 1, 1992, the date of our price data, began on October 1, 1991, and ended on September 30, 1992.

scope of this study, we did conduct a more limited analysis. It examined the effect on differentials of including generic equivalents of the drugs in our sample. In particular, we compared what our market basket of 77 drugs would cost if U.S. consumers purchased the lowest priced generic product in the 21 cases where generic drugs were available and if U.K. consumers always purchased the brand-name product. ¹⁹

We obtained U.K. prices as of May 1, 1992, listed in the Chemist & Druggist Monthly Price List. Because this listing contains wholesale prices rather than manufacturers' prices, we adjusted these prices to factory prices by subtracting the standard 12.5-percent discount that the drug manufacturers provide to U.K. wholesalers.²⁰

All prices in our study reflect what are called transaction prices, rather than list or sticker prices. That is, our price data represent, in general, the actual prices at which manufacturers sell their products to wholesalers and other purchasers in the United States and the United Kingdom. Specifically, for the United States, the wac is the most common basis for U.S. transaction prices in the undiscounted market segment, while the non-FAMP is an average of transaction prices in the undiscounted and other segments.

We converted U.K. drug prices to U.S. dollars using the May 1, 1992, exchange rate of \$0.5598 per dollar. We also converted U.K. drug prices to U.S. dollars using the 1992 purchasing power parity (PPP) of \$0.652 per dollar.

In addition to comparing each drug's U.S. and U.K. factory prices per unit, we summarized the spectrum of price differentials by comparing the cost of purchasing, at factory prices, a weighted market basket of all 77 drugs in the United States to the cost of purchasing the same market basket at factory prices in the United Kingdom. This market basket is, in effect, an index that weights each individual drug price by the quantity of the

¹⁹Generic substitutes were available for 21 of the 77 brand-name drugs in our sample.

²⁰The 12.5-percent discount includes a 10-percent fixed discount provided by the drug manufacturers and set by the U.K. government. In addition, drug manufacturers provide a 2.5-percent prompt-payment discount to wholesalers. According to a representative of the association representing U.K. wholesalers, wholesalers almost always take advantage of this prompt-payment discount.

product sold in the United States.²¹ This comparison of aggregate cost captures the difference between U.S. and U.K. prescription drug prices in a more meaningful way than, for example, the mean or median of the individual differences in unit prices. (See app. III.)

To identify the likely causes of drug price differences across countries, we interviewed U.K. government officials, as well as industry representatives and academic experts in both countries. To learn about the U.K. pharmaceutical market in relation to Europe, we also interviewed representatives of the European Community as well as European government officials, industry representatives, academic researchers, and pharmaceutical industry experts.

U.K. government officials and a pharmaceutical expert in the United States reviewed a draft of this report. Government officials, pharmaceutical industry representatives, and academic researchers reviewed the price comparison methodology described in appendix III. We incorporated their comments as appropriate. Methodological issues for international drug price comparisons are discussed in appendix III.

Manufacturers' Prices for Top-Selling Drugs Typically Higher in the United States Than in the United Kingdom For our sample of top-selling prescription drugs, manufacturers typically charge significantly more in the United States than in the United Kingdom. Our market basket of 77 drugs would cost 60 percent more in the United States than in the United Kingdom. ²² This method of summarizing price differentials gives more weight to drugs that are the most commonly dispensed.

Price differentials between the two countries varied widely among the drugs we studied. The U.S. price ranged from 62 percent lower than the price of the same drug in the United Kingdom to 1,712 percent higher. (See app. II.) Despite this wide range, most drugs were more expensive in the United States than in the United Kingdom. (See fig. I.1.) Of the 77 drugs we compared, 66 drugs were priced higher in the United States while 11 drugs were priced higher in the United Kingdom. Forty-seven drugs (or

²¹These weights are from the IMS America U.S. Drugstore database. IMS America is a private vendor of pharmaceutical information. Its U.S. Drugstore database tracks the pharmaceutical products purchased by independent pharmacies, chain and discount drugstores, and proprietary stores. IMS provided, for calendar year 1992, the number of units sold for all package sizes of the specified strength and form of each drug in our sample.

²²This overall price differential was calculated by converting U.K. prices to U.S. dollars using the May 1, 1992, exchange rate. We also calculated the differential using an alternative conversion method, the 1992 PPP. Using this method, the U.S.-U.K. price differential was 86 percent.